RSQM Associates, LLC
Regulatory, Quality & System Management Consultants

FDA UDI Regulation's Impact on Medical Device Labelers

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Agenda

- Welcome
- Implications for Patient Safety, Adverse Event Monitoring and Electronic Health Records Management
- Review of UDI Final Regulation
- *Draft* Global UDI Database (GUDID) Guidance
- Impact on Entire Organization
- Infrastructure Needed to Implement UDI

US FDA UDI Final Regulation – Global Perspective

- System to track medical devices during their entire lifecycle to help ***reduce medical errors*** and ***improve patient safety***; allowing manufacturers and regulators to determine product and safety issues more quickly and precisely (improved adverse event reporting).
- Eventually easing international product registrations and ultimately prepare the groundwork for a global, ***secure supply chain***, assisting to lower counterfeiting and establishing supply chain effectiveness for manufacturers, distributors and end users.
- Accomplished by creating a "Unique Device Identifier" for medical devices*and recording that information in the Global UDI Database (GUDID).

*Some devices are exempt

FDA UDI Web Site

Supporting Public Health Initiatives and Benefits through…

- FDA's postmarket surveillance programs including:
  - Adverse event reporting (MDR)
  - Device Recalls
  - Electronic Health Records
  - National and international device and specific disease registries
  - Access to large population databases such as claims data
  - Tracking and tracing devices

- Ability to understand patient's/ provider's needs for and use of devices
- Reducing medical errors
- Secure supply chain
- Reducing counterfeiting
- Improved inventory management (shortages/substitutions)
- Disaster/terror preparation
- Easy-to-use and accessible database of device information for all

Will FDA UDI Lead to Global Harmonization?

- EU and other regulatory agencies developing their versions of UDI. Will they be harmonized?
- Benefits to a harmonized global approach to UDI are:
  - Labelers will be able to use a single UDI across all regulators
  - Establish infrastructure for a secure, global supply chain
  - Promote worldwide tracking and tracing
  - Permit automated import review
  - Further global efforts to stop counterfeiting and diversion
  - Backing DoD, WHO and other endeavors requiring international device identification

Key Definitions

- **Automatic identification and data capture (AIDC)** – Any technology that transmits the UDI or other device identifier in a form that can be entered into a computer system or electronic patient record via an automated process.
- **Device package** – a package that contains a fixed quantity of a particular version or model of a device.
- **Expiration date** – the date by which the label of a device must or should be used. Date format is YYYY-MM-DD. **Day is always required**. Applies to ALL labels (even if device is exempt from UDI).
- **Issuing agency** – an organization accredited by FDA to operate a system for the issuance of unique device identifiers.

UDI - Final Rule - Federal Register/Vol. 78, No. 185/Tuesday, September 24, 2013

Key Definitions – Continued

- **Labeler** – the entity taking ***responsibility*** for applying a label to a device being commercially distributed; or replaced or modified with the intent of that the device will be commercially distributed, and adding the device information into the GUDID.
- **Shipping container** – a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another.
- **Version or model** – all devices that have specifications, performance, size, and composition, within limits set by the labeler.

UDI - Final Rule - Federal Register/Vol. 78, No. 185/Tuesday, September 24, 2013

FDA UDI General Guidelines

- Labels* for **ALL** non-exempted medical devices must have a UDI (including IVDs).
- **EACH** device package containing a fixed quantity of a version or model must have a UDI.

Choosing any other path is an exception to or alternative from these requirements.

* FD&C Act Section 201(k) defines "label" as "a display or written, printed or graphic matter upon the immediate container of any article;…"

What is FDA Unique Device Identifier?

DI + PI = UDI

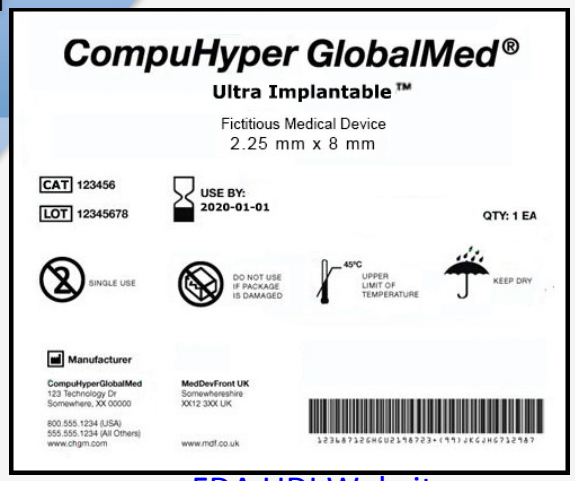
Production Identifier (PI) (dynamic) = one or more of these elements: lot/batch number, serial number, expiration date, manufacturing date

Compare to UPC Label

Device Identifier (DI) (static) = labeler identification + Item code

Labeler Identification*

Item code



*Obtained from GS1, HIBCC or ICCBBA

FDA UDI Website

Details…It's Always The Details

1. Establish and assign DIs
   a. Obtain labeler ID from FDA accredited issuing agencies – GS1, HIBCC or ICCBBA/ISBT-128
   b. Designate DIs to ALL devices (kits, combination devices, complex systems, configurable items)
2. Incorporate UDI (DI+PI) on to device label
   a. Plain text (human readable) **and** AIDC technology
   b. If AIDC not evident – mandates the label "disclose" presence of AIDC technology

More Details

3. Direct Marking (also requires package label)
   a. Device intended to be used more than once, and
   b. Intended to be "**reprocessed**" before each use
   c. "Reprocessed" – clean, clean + disinfected or clean + sterilized (for now)
4. Stand-Alone Software
   a. Is your SAS a regulated device?
   b. UDI in "Help," "About" or start-up screens
   c. Version = lot
5. "1 in 1" Devices
   a. UDI on package

There Are Always Exceptions…

- Class I Devices Exempt from GMP (exclusive of ongoing requirement for record keeping under §820.180 and §820.198).
- Individual single-use devices (excluding implanted devices). Packaging must have UDI.
- Device as part of a combination product or kit, as long as the kit package label has a UDI.
- Shipping containers.
- UDI for Class I Devices do NOT need PIs included.
- Direct Marking
  - Interfere with safety or effectiveness of device
  - Technologically infeasible
  - "Reprocessed" single-use device
  - Previously marked

Must be noted in DHF – no need to submit exception request.

and there are others….

Request for Exception/Alternative

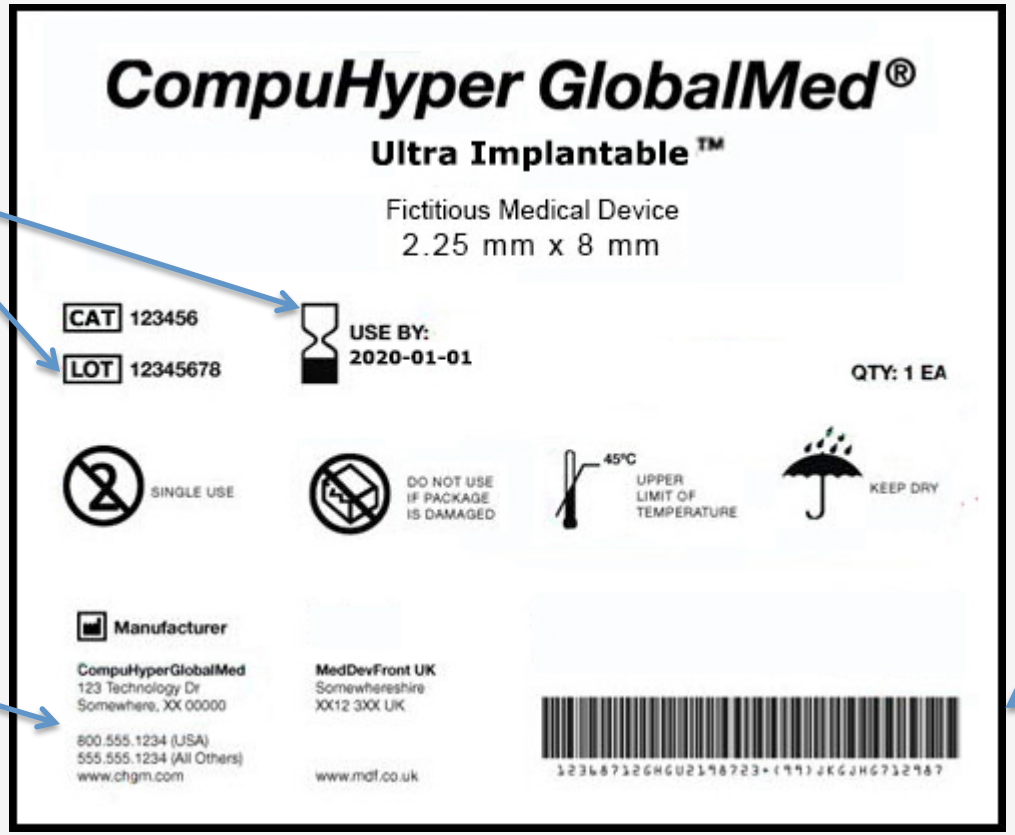
1. Pinpoint device(s) subject to exception/alternative
2. Pinpoint provisions of Subpart B (§801.55) subject to request
3. Exceptions – justify why requirements are ***not technologically feasible***
4. Alternatives – describe and explain –
   a. "…why it would provide more ***accurate, precise, or rapid device identification***…"
   b. "…how the alternative would be would be ***ensure the safety or effectiveness*** of the device…"
5. If known, provide number of labelers/devices that would be affected
6. Other information as requested

When Is A New DI Required?

- Devices
  - Device changes resulting in new version or model
  - A new device package is created
  - No relationship to premarket notifications
- Stand-Alone Software
  - Minor vs. Major changes (see IMDRF guidelines)
  - Minor (new PI) – generally bug fixes, security patches, non-safety related usability improvements
  - Major (new DI) – changes affecting safety, intended use, performance or effectiveness

UDI Label Example

Expiration Date & Lot Number are examples of PI

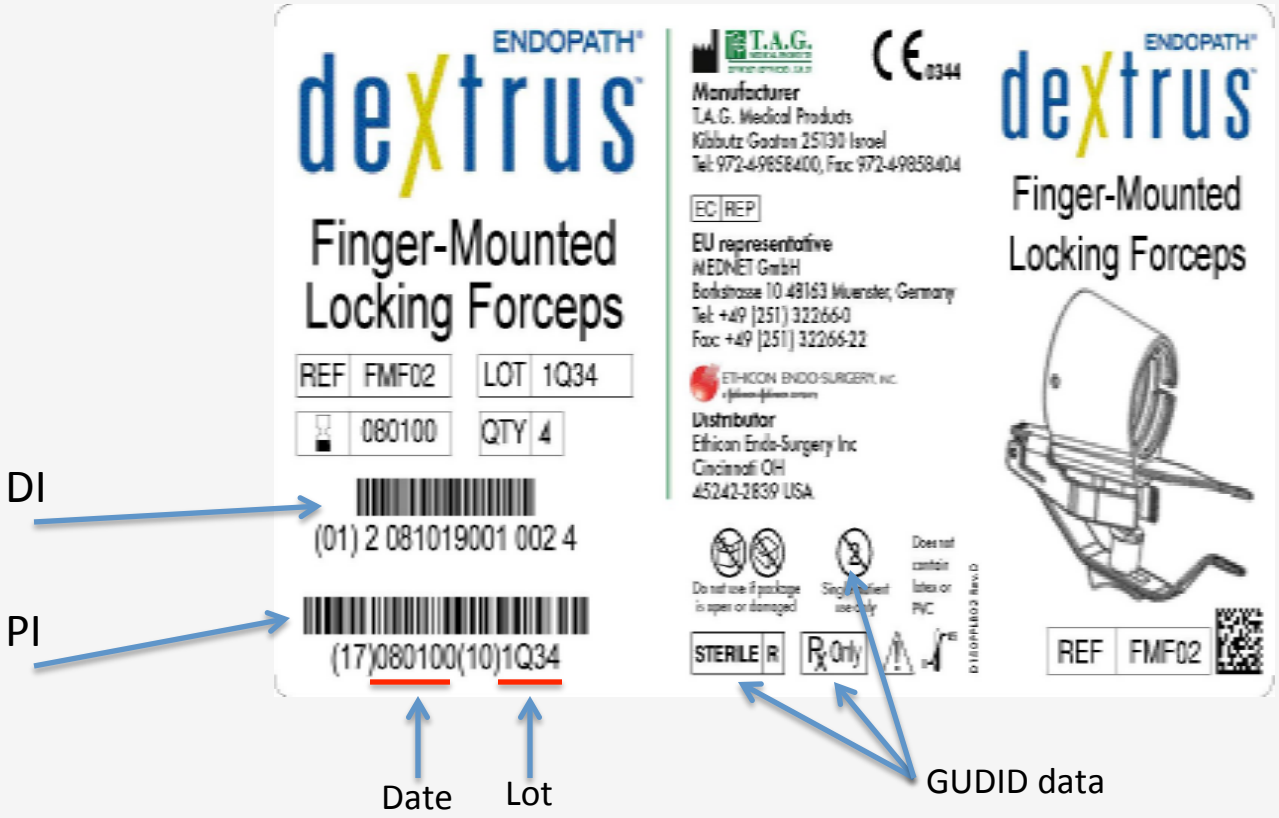


Manufacturer address required element on label

UDI Barcode containing DI + PI information

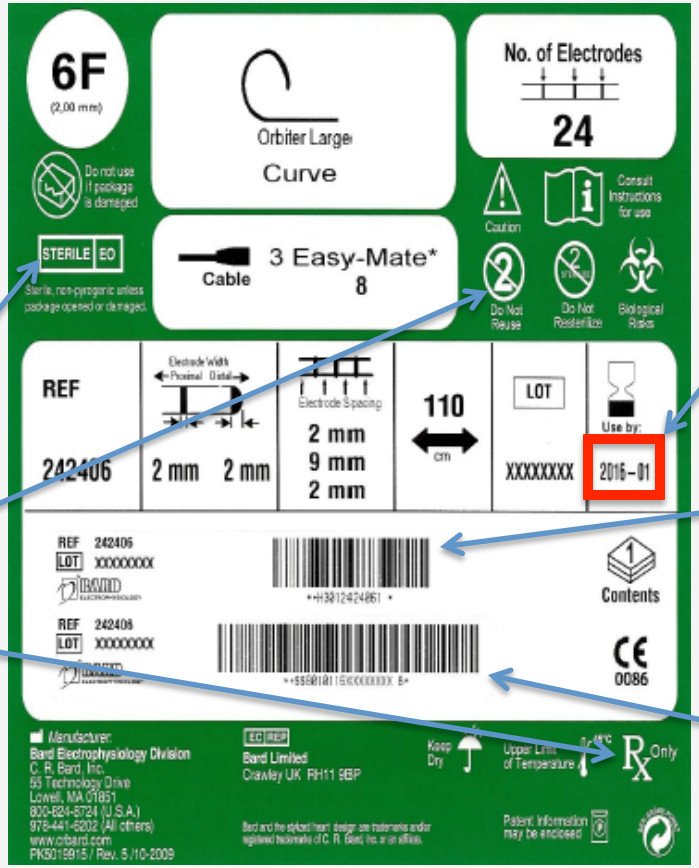
[FDA UDI Website]

UDI Label Examples – GS1



[Jay Crowley Presentation - CDRH Learn Course List - UDI System]

UDI Label Example - HIBCC



Date missing "day"

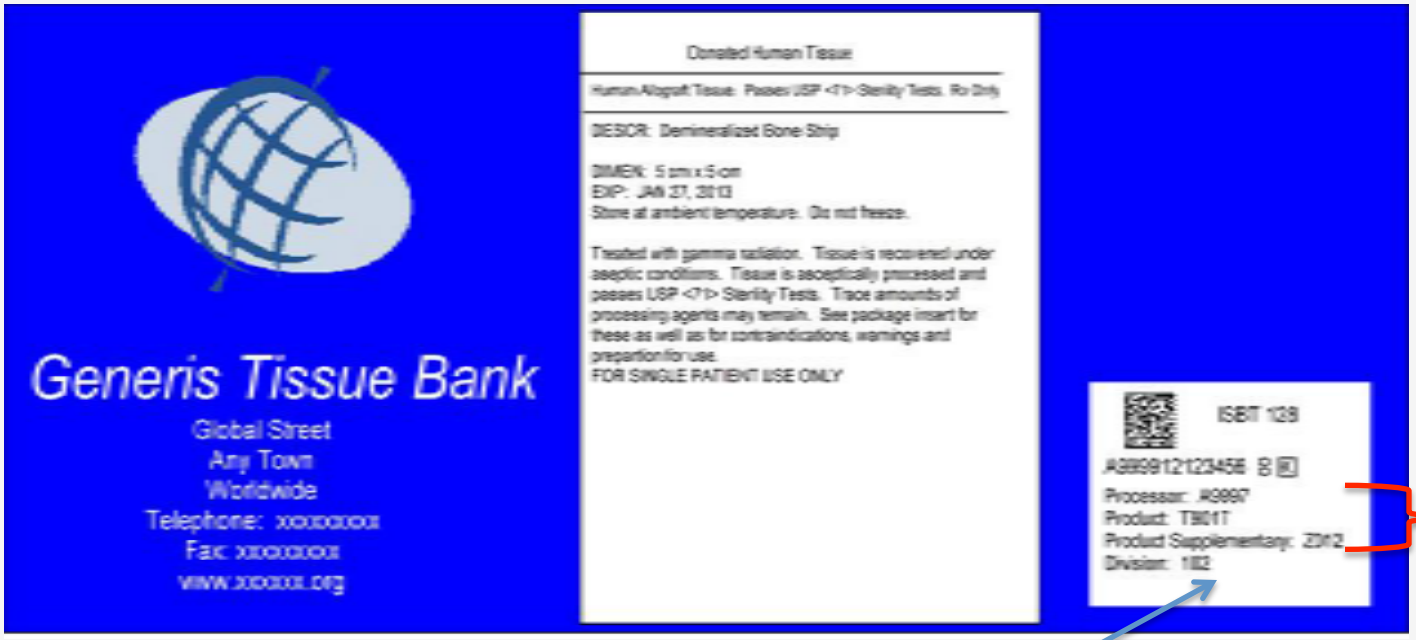
DI

GUDID Data

PI

[Jay Crowley Presentation - CDRH Learn Course List - UDI System]

UDI Label Example - ISBT-128



ISBT-128 Area of Label

Device Identifier = A9997T9017Z012

Processor Identifier (assigned by ICCBBA) A9997 = Labeler

Production Identifier = A999912123456102

Lot number = A999912123456 (Donation Identification Number)

Serial Number = 102 (Division)

Jay Crowley Presentation - CDRH Learn Course List - UDI System

Timelines – Don't Panic Just Yet, unless…

Compliance Date	Requirements
September 24, 2014* Labels and packages of: **Class III devices [§801.20], plus…**	• **Class III stand alone software [§801.50(b)]** • **Devices licensed under the Public Health Service Act [§801.20]** • **Dates on labels must be formatted as YYYY-MM-DD [§801.18]**** • **Data for these devices must be submitted to GUDID [§830.300]**
September 24, 2015 Labels and packages of: **Implantable, life-supporting & life-sustaining devices [§801.20], plus…**	• **Life-supporting/life-sustaining Stand-Alone Software must have UDI [§801.50(b)]** • **Life-supporting/life-sustaining devices must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]** • **Dates on labels must be formatted as YYYY-MM-DD [§801.18]**** • **Data for these devices must be submitted to GUDID [§8300.300]**
September 24, 2016 Labels and packages of: **Class II devices & Software [§801.20], plus…**	• **Class III devices must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]** • **Dates on labels must be formatted as YYYY-MM-DD [§801.18]**** • **Data for these devices must be submitted to GUDID [§830.300]**
September 24, 2018 Labels and packages of: **Class I devices & Software [§801.20], plus…**	• **Class II devices must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]** • **Devices that have not been classified as Class I, Class II or Class III [§801.20]** • **Dates on labels of ALL devices, including devices exempted from UDI labeling requirements must be in YYYY-MM-DD format [§801.18]**** • **Data for these devices must be submitted to GUDID**
September 24, 2020 **The final hurrah…**	• **Class I devices and devices that have not been classified as Class I, Class II or Class III must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]**

*June 23, 2014 Request 1-year extension

**Human Readable Date only. Does not apply to dates in AIDC technology.

Some Breathing Room….

- Exception to Compliance Dates
  - Class III/PHS Act devices
    - 1-year extension of September 24, 2014 compliance date may be requested under §801.55
    - Must be submitted no later than June 23, 2014
  - Inventory on-hand (labeled prior to the compliance date) for up to 3 years after the compliance date.

FDA Global UDI Database

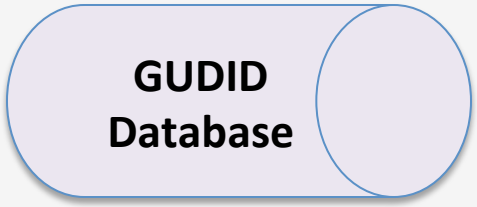
- GUDID ("Good-I-D") will be a publically searchable database* of every medical device required to have a UDI
- Contains only DI information, plus additional device attributes – 60+
- Data can be submitted via GUDID Web interface or GUDID HL7 SPL.
- Labelers required to request GUDID account (Class III & PHS medical device labelers only at this time)
- Requires DUNS Numbers
  - Organization DUNS (can be labeler DUNS)
  - Labeler DUNS
  - Third Party DUNS
- Labeler organization can have multiple GUDID accounts
- Required to identify Regulatory Contact, GUDID Coordinator(s) and GUDID Labeler Data Entry User(s)

*Turned off until enough data has been submitted.

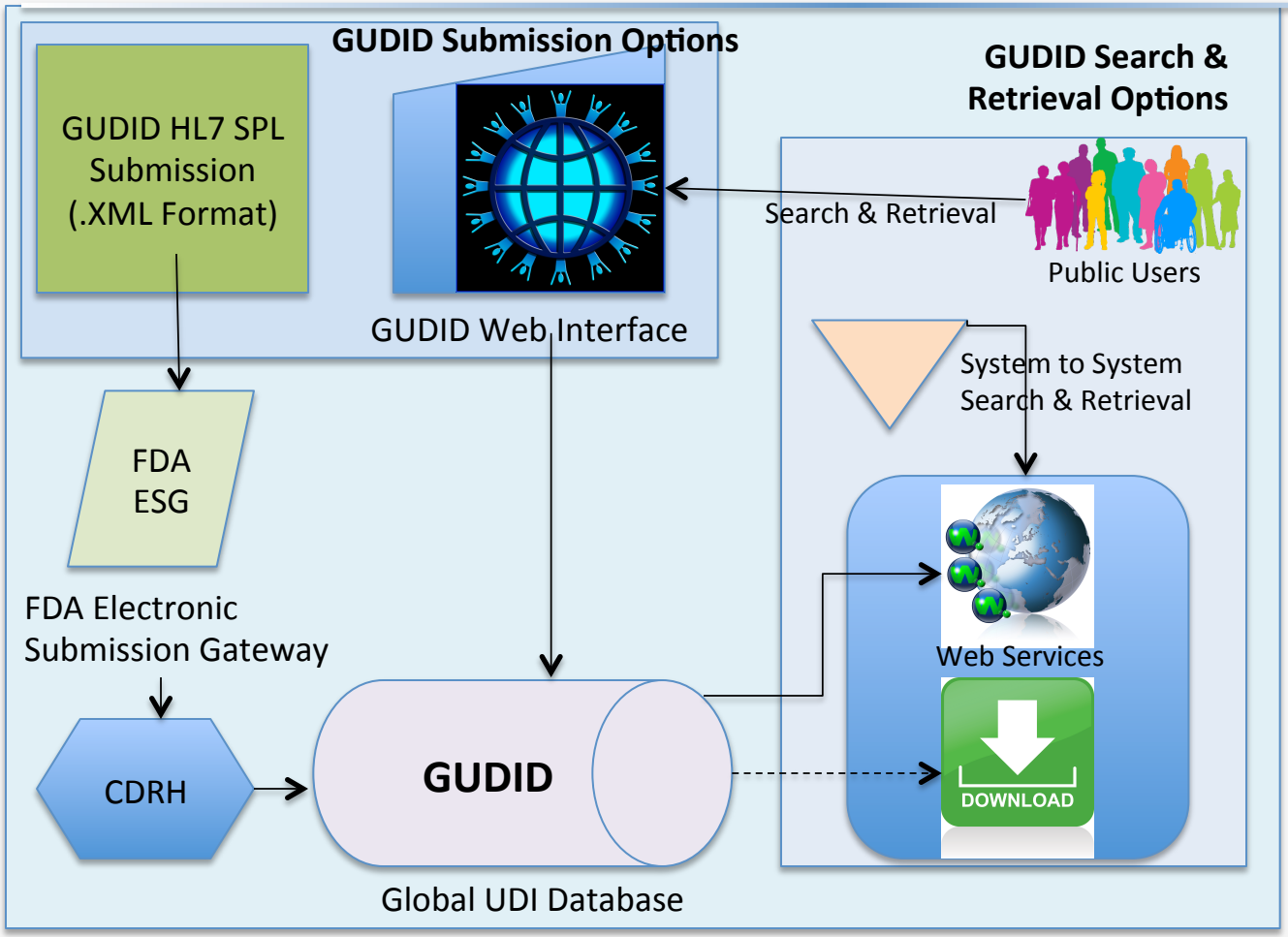
FDA Global UDI Database (GUDID) Website

FDA Global UDI Database

- Changes from proposed UDI rule –
  - Now requires submission of Global Medical Device Nomenclature (GMDN) code/term for each device
    - FDA providing free access to GMDN codes during submission process
  - Magnetic Resonance Imaging (MRI) compatibility (Safe, Conditional, Unsafe) submission required for devices labeled as such



GUDID Submission Overview



1. Submission Options
   a. One record via Web
   b. One record per XML via HL7 SPL submission through FDA ESG
2. Search & retrieval capabilities are currently not operational

FDA GUDID Data Fields

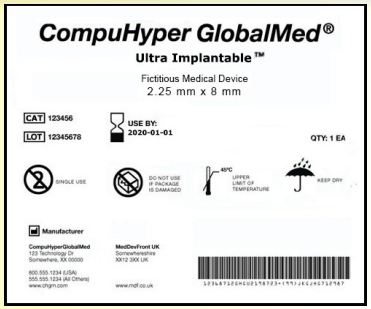
Labeler	Regulatory	Production	Characteristics
Labeler DUNS Number^	Publish Date	Lot/Batch Number (Y/N)	Single Use (Y/N)
Company Name*	Distribution End Date	Manufacturing Date (Y/N)	Combination Product#
Company Physical Address*^	Distribution Status*	Serial Number(Y/N)	HTC/P#
Customer Contact Phone	Premarket Exempt#	Expiration Date (Y/N)	Contains Rubber (Y/N)
Customer Contact E-Mail	Premarket Submission No.	Donation ID Number (Y/N)	Labeled 'Not made with Rubber'#
Device Identification (DI)	Supplement Number	**Packaging**	MRI Safety
Issuing Agency	FDA Listing Number	Device Count	Size Type
Primary DI Number	FDA Product Code	Unit of Use DI Number	Size Value
Brand Name	FDA Product Code Name*	Kit#	Size Unit of Measure
Version/Model Number	GMDN Code	Package DI Number	Size Type Text
Catalog Number	GMDN Name*	Quantity per Package	Storage & Handling Type
Device Description	GMDN Definition*	Package Contains DI Number	S&H Low Value
Second DI Issuing Agency	Prescription#	Package Type^	S&H High Value
Secondary DI Number	Over-the-Counter#	Package Discontinue Date	Storage & Handling Unit
Subject to DM, but Exempt#		Package Status*	Special Storage Conditions
DM DI Different (Y/N)#			Sterile Package (Y/N)
DM DI Number			Sterile Required (Y/N)
			Sterile Method

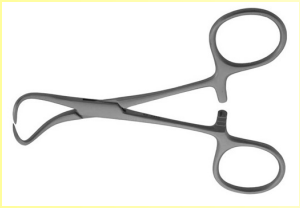
^Data elements not released to public *FDA GUDID System completes these fields #Checkbox

Putting It All Together…

Label Requirements

- UDI (Device ID + Production ID) on Device Label & Package
- In human-readable and AIDC technology
  - RFID, 1D/2D barcode, near-field communication
  - AIDC to be visible, if not, add disclosure
- Date format – YYYY-MM-DD (2018-08-08)
- Direct Marking (DM)
  - Requires UDI label (on package)
  - Device intended to be used more than once, and
  - Intended to be "reprocessed" before each use
- Direct Part Marking (DPM)
  - As needed for certain devices
- Device Software to have UDI in "About," "Help" or when software is started





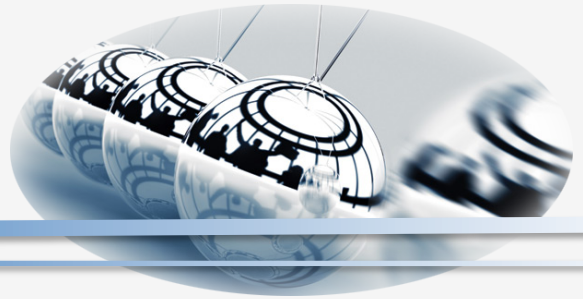
FDA Global UDI Database (GUDID)

- Submit DI (exclude PI) and required attributes
- Web based tool or HL7 SPL or 3rd Parties (e.g., GDSN)
- Public interface

Postmarket Surveillance

- Include UDI as available
- Improved adverse event reporting
- Improved Public Safety

Organizational Impact



- "Publish or Perish" – medical device labelers must comply with regulation regardless of cost
- Establish corporate UDI policy and strategy
  - Requires full participation from top management
- Identify UDI Champion and implementation team
- Develop Master Data Management (MDM) plan
- Implement changes to SOPs as required
- Determine all departments impacted
- Implement changes to budgeting process

Impact to Existing Regulations

Part	Subpart	Section(s)	Conforming Amendments
801-Labeling	A	§801.18 (a)(b)	New date format YYYY/MM/DD
	B	New section	Adds labeling requirements for UDI
803-Med. Dev. Rptg	C	§803.32; §803.33; §803.42; §803.53	Adds UDI as requirement
806-Corrections & Removals	B	§806.10; §806.20	Adds UDI as requirement
810-Med. Dev. Recall	B	§810.10	Adds UDI as requirement
814-Premarket App.	E	§814.84	Adds UDI as requirement
820- Quality System	K	§820.120	Labeling inspection – added requirement to inspect UDI
	M	§820.184	Requires adding UDI or UPC to record
	M	§820.198	Requires including UDI or UPC in investigation report
	M	§820.200	Requires including UDI or UPC in service report
821-Tracking Requirements	B	§821.25	UDI to be provided to FDA when requested (single/multi-patient use
	C	§821.30	Adds UDI as requirement
822-Post Market Surveillance Plan	C	§822.9	Adds DI to information to be provided

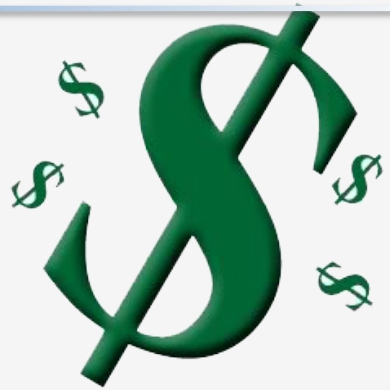
Overall Cost Impact

- Significant cost to industry, especially to small businesses. "The final rule may have a significant economic impact on a substantial number of small entities that label medical devices." Pg. 58813 FR Vol 78, No 185, 9/24/2013

- Eastern Research Group, Inc under contract to FDA, "… estimated present value of the costs to domestic labelers is $620.4 million using a 7 percent discount rate and $713.2 million using a 3 percent rate…" over a 10-year period.

- Most costs will be for planning, administration, UDI integration into existing information systems, barcode printer setup and testing, training employees, label re-design (including change in date format), and more.

Ongoing Costs



- Issuing Agencies - Each has own cost structure
  - GS1 – (www.gs1us.org/healthcare)
    - Initial registration fee plus annual renewal
    - Annual fee based on number of items
  - HIBCC – (www.hibcc.org)
    - Initial registration fee
    - One-time fee for Labeler Identification Code based on company's gross annual sales
  - ICCBBA – (www.iccbba.org)
    - Annual license fee is based on type of organization
- GMDN (www.gmdnagency.com)
  - Fees are based on annual revenues (per million Euros) and number of codes needed
  - Additional code "packs" can be purchased
- Continued maintenance of system

What Steps Do You Need To Take? 1/3

1. Examine, Strategize and Prepare Plan:
   a. Select Issuing Agency that will best meet needs.
   b. Categorize products by Class, Manufacturing Location, Label, Packaging Requirements, other criteria as needed.
   c. Determine shortfalls between UDI obligations and current labeling and packaging practices, software systems (PLM, ERP, etc.), integration with GUDID, current SOPs, supply chain systems.
   d. Create strategic plan and schedule (details, budgets, assignments, partners) to:
      - Address needs in PLM/ERP and supply chain systems, labeling/ packaging equipment and procedures, and labels/packaging
      - Define gateway to GUDID
      - Create validation and compliance plans of action

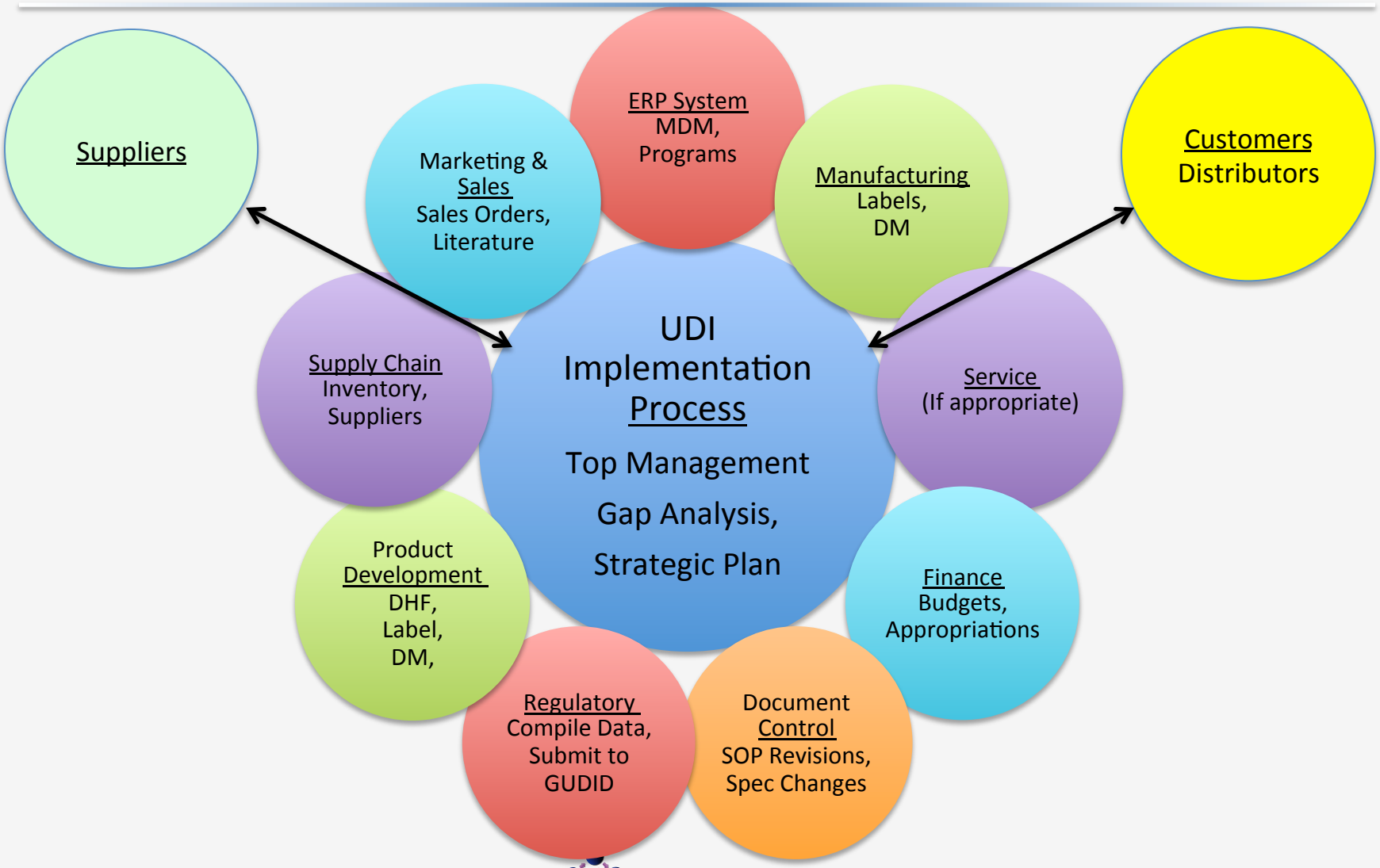
What Steps Do You Need To Take? 2/3

2. Construct and Enact
   a. Amend label/packaging composition and components; order by compliance date
   b. Compose, establish, administer and validate software system changes and integrations
   c. Acquire new or upgrade existing labeling and packaging equipment and validate
   d. Rehearse connectivity with GUDID and validate all systems are functioning correctly
   e. Create/revise SOPs as needed and conduct process validation
   f. Training programs for UDI implementation

What Steps Do You Need To Take? 3/3

3. Post Implementation Processes
    a. Supervise transition to manufacturing of the first run of each product
    b. Coalesce UDI requisites into product development process and new models/ versions of current products
    c. List new product and new models/versions of current products with GUDID
    d. Continual training of UDI requirements

Looking At The Entire Organization



Thank you!

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